UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,966	12/05/2001	Wesley H. Verkaart	70869-0083	1396

41883 7590 04/17/2006

HAEMONETICS CORPORATION
400 WOOD ROAD
BRAINTREE, MA 02184-9114

EXAMINER	
SAUCIER, SANDRA E	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/001,966	VERKAART ET AL.	
	Examiner	Art Unit	
	Sandra Saucier	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-11,21 and 23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11,21 and 23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-4, 6-11, 21, 23 are pending and are considered on the merits.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103

Claims 1-4, 6-11, 21, 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,407,425 [A] in combination with Dorner *et al.* [U] and US 5,879,318 [IDS].

The claims are directed to a method for separating red cells from a mixture (having a hematocrit about 30-64) comprising shed blood, anticoagulant (CPD or heparin) and a washing solution (starch), by sedimentation in the absence of centrifugation. The sedimented cells are then reinfused.

The references are relied upon as explained below.

US 5,407,425 teaches a method of collecting blood from a patient, separating the red cells from the blood by gravity using an anticoagulant and hydroxyethylstarch and reinfusing the red cells (col. 2, ls. 30-55). The system may be used for interoperative aspiration of blood (col. 2, l. 65). The anticoagulant is may be a citrate type anticoagulant. The reference lacks the use of the specific anticoagulants CPD or heparin.

Dorner *et al.* teach a method of separation of red cells from a mixture having a hematocrit of 30-35 comprising blood, CPD and hydroxyethylstarch by gravity sedimentation. (Materials and Methods, page 440). Dorner *et al.* teach the time for gravity sedimentation using CPD/HES is about 25 minutes. In Fig 1, times of sedimentation up to 35 minutes are exemplified. The red cells are transfused after concentration (page 440, 1st column, middle of the page).

US 5,879,318 discloses a composition comprising blood, CPD and a rouleaux reagent comprising Hetastarch (col. 5, l. 48, and col. 6, l. 20-29 and claim 3. The HES solution is 6% (col. 3, l. 21). The blood/anticoagulant 7:1 mixture (col. 5, l. 47) is mixed with the starch and the red cells sedimented (col. 6, l. 1-9) and the supernatant containing the white cells is removed (col. 5, l. 31-38). US 5,879,318 further teaches the use of heparin among other anticoagulants and exemplifies CPD as the anticoagulant of choice in a composition comprising blood, anticoagulant and HES (col. 4, l. 44). The use of a short centrifuge spin red cells aids in the sedimentation of the red cells (col. 2, l. 26) is an optional aid in the sedimentation process. Thus, the reference teaches both sedimentation under gravity alone and aided by mild centrifugation.

The substitution of heparin or CPD in the rouleaux formation and reinfusion of red cells disclosed in the method of US 5,407,425 would have been obvious when the method of US 5,407,425 was taken with Dorner et al. or US 5,879,318 which teach the use of either CPD or heparin in rouleaux formation.

It would have been obvious to use heparin as an anticoagulant in a ratio of 1/7 in a process of adding HES, preferably between 1-6% (col. 4, l. 40) and forming a mixture of blood, heparin 7/1 and 6% HES in order to sediment red cells according to the method of '425 because '318 generically teaches this method.

It would have been obvious to allow the red cells to sediment by gravity for about 20 minutes when '425 was taken with Dorner *et al.* because Dorner *et al.* disclose the time for gravity sedimentation with anticoagulant (CPD)/HES is about 25 minutes.

One of ordinary skill in the art would have been motivated at the time of invention to make this substitution in order to obtain the results as suggested

by the reference with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

In short, the method as claimed is old and known in the art. No claim is allowed. Applicant is invited to present a showing of unexpected results in order to advance prosecution.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-11, 21, 23 have been considered but are moot in view of the new ground of rejection.

Conclusion

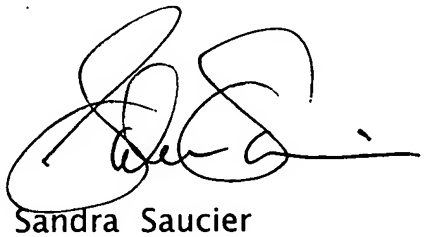
Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (571) 272-0922. The examiner can normally be reached on Monday, Tuesday, Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, M. Wityshyn can be reached on (571) 272-0926.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sandra Saucier
Primary Examiner
Art Unit 1651
April 13, 2006